

REMARKS/ARGUMENTS

The present Response to the June 30, 2004 Advisory Action is identical to the Response and Amendment under 37 C.F.R. § 1.116 filed on May 18, 2004, with the exception that the requests for correcting inventorship are not presented herewith because the Advisory Action indicates that these requests have been acknowledged by the Examiner and the application is being forwarded to the OIPE for issuance of a corrected filing receipt. Applicants thank the Examiner for this consideration and acknowledgement and consider this acknowledgement as entry in part of the May 18, 2004 Response.

Claims 18-20 and 26 have been amended. Claims 1-7, 16, 21-25, and 29-46 have been withdrawn from consideration. Claims 42-44 have been cancelled without prejudice or disclaimer. Claims 1-41 and 45-55 remain pending in this application upon entry of this amendment.

Claim 18 has been amended to recite “An isolated oligonucleotide of no more than 100 nucleotides comprising at least 20 consecutive nucleotides of SEQ ID NO: 1, that hybridizes under stringent conditions with a nucleic acid having a nucleotide sequence as depicted in SEQ ID NO: 1, said stringent conditions including 50% formamide, 4XSSC at 42° C.” Claim 19 has been amended to recite “...at least 30 nucleotides are contiguous nucleotides of SEQ ID NO: 1...” Claim 20 has been amended to recite “an oligonucleotide,” so that it refers correctly to the claim from which it depends (claim 18). Support for these amendments can be found throughout

the specification and in particular on page 19, lines 25-27, page 20, lines 5-17; and page 22, lines 6-13 of the specification.

Withdrawn claim 26 has been amended to incorporate the limitations of claims 42-44 (accordingly, claims 42-44 have been canceled). Support for this amendment can be found throughout the specification and in originally filed claims 42-44.

No new matter has been added by way of these amendments.

Claim Objections

Claim 19 was objected to being of improper dependent form for failing to further limit the subject matter of the claim it depended on. Specifically, the Examiner contends that claim 19 was drawn to a polynucleotide comprising ten consecutive nucleotides of SEQ ID NO: 1, while claim 18 (the claim from which claim 19 depends) recited a polynucleotide comprising 20 consecutive nucleotides of SEQ ID NO: 1.

Claim 19 has been amended to recite “wherein at least 30 nucleotides are contiguous nucleotides of SEQ ID NO: 1.” Claim 19 now requires that at least 30 nucleotides are contiguous nucleotides of SEQ ID NO: 1, while claim 18 requires only at least 20 contiguous nucleotides of SEQ ID NO: 1. Thus, it is believed that the objection to claim 19 has been overcome and Applicants respectfully request its withdrawal.

Rejections under 35 U.S.C. § 112, first paragraph- written description

Claims 18-20 have been rejected for failure to fulfill the written description requirement because the claims are allegedly drawn to a large variable genus of DNA molecules encoding many different proteins or a large variable genus of polynucleotides with unknown function. In addition, the Examiner alleges that many structurally and functionally unrelated DNA are encompassed within the scope of the claims, including partial DNA sequences. Finally, the Examiner alleges that the specification fails to describe representative species encompassed by the genus of the claim.

In view of the amendments made to claims 18-20 and the arguments presented herewith, Applicants respectfully request withdrawal of this rejection. Claim 18, as presently amended, is not drawn to DNA molecules that encode proteins, as it has been amended to recite that it is directed to an oligonucleotide. As established on, for example, page 19, lines 25-27, page 20, lines 5-17, and page 22, lines 6-13 of the specification, the present invention describes and contemplates oligonucleotides that are at the most 100 nucleotides in length, that comprise at least 20 contiguous nucleotides of SEQ ID NO: 1, and that hybridize under stringent conditions to SEQ ID NO: 1. The specification (see e.g. page 19, lines 5-27) and claim 18 sets for the requisite hybridization conditions to perform hybridization of the oligonucleotide, describes that oligonucleotides can be made via numerous methods or isolated from an EER-7 fragment (see e.g. page 20, lines 5-17, and page 22, lines 6-13), and describes the entire SEQ ID NO: 1 (see Sequence Listing).

In view of the above arguments and the amendments to claims 18-20, Applicants submit that the present application fully describes the presently claimed oligonucleotides. Accordingly, Applicants respectfully request withdrawal of these rejections.

Rejections under 35 U.S.C. § 112, first paragraph- enablement

Claims 18-20 have also been rejected for failure to fulfill the enablement requirement because the specification allegedly does not teach how to use polynucleotides of 20 nucleotides that will hybridize to allegedly wide range of polynucleotides/oligonucleotides. The Examiner also alleges that it is unpredictable if a polynucleotide that hybridizes to SEQ ID NO: 1 will not also hybridize to other lysyl oxidases under defined stringent conditions.

In view of the amendments made to claims 18-20 and the arguments presented herewith, Applicants respectfully request withdrawal of this rejection. Claim 18 has been amended to delete the limitation that the nucleotides “do not hybridize under stringent conditions to nucleic acids encoding other lysyl oxidases” and has been amended to recite an oligonucleotide that has no more than 100 nucleotides. This latter amendment significantly limits the number of polynucleotides encompassed by the claim. One of ordinary skill in the art would readily know how to design and use oligonucleotides that were 100 nucleotides or less in length, that comprise at least 20 consecutive nucleotides of SEQ ID NO: 1 and that hybridize under specific stringent hybridization conditions (e.g. 50% formamide, 4XSSC at 42° C) to SEQ ID NO: 1. It would be routine for one of ordinary skill in the art to screen for oligonucleotides that are at most 100

nucleotides in length and that comprise at least 20 consecutive nucleotides of SEQ ID NO: 1 and that hybridize under stringent conditions to SEQ ID NO: 1. In addition, the specification provides disclosure in the specification that would enable one to make or isolate the presently claimed oligonucleotides (see e.g. page 8, lines 20-23; page 18, lines 2-6; page 18, line 28 - page 19, line 27; and page 23, lines 6-8 of the specification).

In view of these arguments and the amendments made to claims 18-20 it is believed that these rejections have been obviated and sufficiently addressed. Accordingly, withdrawal of these rejections is respectfully requested.

Rejections under 35 U.S.C. § 102(b)

The Examiner has rejected claims 18-20 for allegedly being anticipated under 35 U.S.C. § 102(b) by Bonaldo (Genome Res. 6(9), 791-806 (1996)). Specifically, the Examiner contends that Bonaldo teaches a polynucleotide that is at least 20 consecutive nucleotides in length that hybridizes to SEQ ID NO: 1 under stringent hybridization conditions.

Claim 18, which is the claim from which claims 19 and 20 depend, has been amended to recite “An isolated oligonucleotide of no more than 100 nucleotides comprising at least 20 consecutive nucleotides of SEQ ID NO: 1....” Bonaldo discloses a nucleic acid that is greater than 100 nucleotides. Thus, is believed the rejection of claims 18-20 as anticipated by Bonaldo has been overcome and withdrawal of this rejection is believed to be in order.

Rejections under 35 U.S.C. § 102(e)

Claims 8-10, 13-15, 17-20, and 47-55 have been rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Publication No. US 2003/0059919 (U.S.S.N. 10/160,501; herein the “Second Meyers application”). The Second Meyers application was filed on May 30, 2002 and is a continuation-in-part of several applications, each of which claims priority to a provisional application. One of these applications that the Second Myers application claims priority to (as a continuation-in-part) is U.S. Publication No. US 2002/0068322 (U.S.S.N. 09/870,110; herein the “First Meyers application”), which was the basis of the Examiner’s rejection of claims 2-10, 13-15 and 17-20 under 35 U.S.C. § 102(e) in the previous Office Action (mailed April 8, 2003). The First Meyers application was filed on May 29, 2001 and claims priority to provisional application 60/207,650 (“the ‘650 provisional application”, entitled “47765, a novel human lysyl oxidase and uses thereof”), filed May 26, 2000. As shown in the documents attached at Tab 1 (which are from the USPTO’s Patent Application Information Retrieval (PAIR) database), the ‘650 provisional application is the earliest filed application to which the Second Meyers application claims priority that was directed to the subject matter claimed in the present application. The documents attached at Tab 1 show that the only applications to which the Second Meyers application claims priority that date prior to the filing date of the ‘650 provisional application (May 26, 2000) were directed to subject matter other than lysyl oxidases (U.S.S.N. 60/197,747 was directed to 39228, a human alcohol dehydrogenase and uses therefor; U.S.S.N. 60/205,449 was directed to a 55158, a human carbonic anhydrase and uses thereof; and

U.S.S.N. 60/205,961 was directed to 32263, a human biotin enzyme and uses therefor). Thus, the alleged effective date of the subject matter allegedly relevant to the instant application in the Second Meyers application, like the First Meyers application, is May 26, 2000. However, Applicants do not concede that either the First or Second Meyers applications are entitled to an effective filing date of May 26, 2000.

Accordingly, Applicants herein submit the same Declaration under 37 C.F.R. § 1.131 that was used to remove the First Meyers application as prior art against the instant application (i.e. the same declaration as that which was annexed to the Response and Amendment mailed on October 8, 2003). Each of the averments made by the inventors in the Declaration under 37 C.F.R. § 1.131 of Mark J. Evans, Marshall S. Scicchitano, Ashok R. Bapat, Ramesh A. Bhat, Robert Mastroeni, and Sotirios K. Karathanasis to swear behind the First Meyers application are being applied herewith to swear behind the Second Meyers application.

37 C.F.R. § 1.131 states that “The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference...” The Declaration that was used to remove the First Meyers application as prior art against the instant application, establishes conception and reduction to practice of the presently claimed invention at a date prior to the earliest possible date the disclosure related to lysyl oxidases (e.g. pages 413-415 of the Second Meyers application) in the Second Meyers application is entitled to.

The annexed Declaration of Mark J. Evans, Marshall S. Scicchitano, Ashok R. Bapat, Ramesh A. Bhat, Robert Mastroeni, and Sotirios K. Karathanasis under 37 C.F.R. § 1.131

establishes that the instant invention was conceived and completed at a time prior to May 26, 2000, the alleged effective date of the Second Meyers application.

The documents submitted herewith as Exhibit 1 establish that Mark J. Evans, Marshall S. Scicchitano, Ashok R. Bapat, Ramesh A. Bhat, Robert Mastroeni, and Sotirios K. Karathanasis conceived and completed the instant invention at a date prior to May 26, 2000. Page 1 of Exhibit 1 shows that the inventors had the clone D3E11 in their possession at a time prior to May 26, 2000 and that this clone had a cDNA insert of the expected size for a full length EER-7. Pages 2-3 of Exhibit 1 show that the inventors had obtained the full-length nucleotide sequence of EER-7 at a time prior to May 26, 2000. The Declaration under 37 C.F.R. § 1.131 also establishes that the documents submitted herewith as Exhibit 1 was created at a time prior to May 26, 2000.

In view of the Declaration under 37 C.F.R. § 1.131, the anticipation rejection in view of the Second Meyers application is moot; the Second (Meyers application is not available as prior art against the instant application under 35 U.S.C. § 102(e)). Accordingly, Applicants respectfully request withdrawal of this rejection.

Rejections under 35 U.S.C. § 102(g)

The Examiner has rejected claims 8-10, 13-15, 17-20, and 47-55 as anticipated by the Second Meyers application (U.S. patent application publication No. 2003/059919) under 35 U.S.C. § 102(g).

The Examiner alleges that the Second Meyers application teaches a DNA molecule encoding a lysyl oxidase that is 99.9% identical to SEQ ID NO: 2, differing only by one amino acid at position 405. The Examiner also alleges that the Second Meyers application teaches vectors comprising this DNA, host cell transfected with the vector, a method of producing the protein and nucleic acid molecules of at least 20 bases that hybridize under stringent conditions with SEQ ID NO: 1 that are labeled.

Applicants acknowledge that the Second Meyers application teaches a DNA molecule that is 99.9% identical to SEQ ID NO: 2, differing only by one amino acid at position 405. Accordingly, the Second Meyers application has interfering subject matter with the instant claims. Applicants point out that the Second Meyers application has not issued as a patent. In addition, Applicants respectfully point out that the instant application is entitled to an effective filing date of August 8, 2000 via U.S. provisional application 60/223,763; August 8, 2000 is less than three months from the alleged effective date of the Second Meyers application (May 26, 2000).

